

Appln. No. 10/620,012  
Amdt. dated May 1, 2006  
Reply to Office Action of February 1, 2006  
Docket No. 7280-2-1

### **REMARKS/ARGUMENTS**

These remarks are made in response to the Non-final Office Action of February 1, 2006 (Office Action). As this response is timely filed before the expiration of the 3-month shortened statutory period, no fee is believed due.

In the Office Action, Claims 1-30 were rejected under 35 U.S.C. 102 (e) as being anticipated by U.S. Published Patent Application 2004/0073095 A1 to Causey III, *et al.* (hereinafter Causey). Applicant has amended independent Claims 1, 12, 19, and 25 to emphasize certain aspects of Applicant's invention. Applicant also has amended Dependent Claims 3-5, 8, and 10 to further emphasize certain aspects of the invention and to maintain consistency among the claims. The claim amendments, as discussed herein, are supported throughout the Specification. (See, e.g., Specification, paragraphs 0027, 0030, 0033, 0038, and 0046.) No new matter has been introduced by the claim amendments.

### **Applicant's Invention**

It may be useful to reiterate certain aspects of Applicant's invention prior to addressing the cited reference. One embodiment of the invention is a health monitoring device. The device can be worn, for example, by a patient or other person needing heightened monitoring for a medical condition. The device, more particularly, can include a plurality of sensors configured to monitor health indicators of the wearer of the device, along with a sensor interface for receiving health indicator data from each of the sensors. The device also can include at least one memory for storing the health indicator data, and a processor for analyzing the health indicator data. Moreover, the processor can be configured to dynamically regulate a substance delivery mechanism responsive to the health indicator data

Additionally, the device can include a wireless transmitter connected to the processor. The transmitter can be activatable both (a) manually by the wearer and (b)

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transmitter can detect the presence of an in-range wireless receiver and, in response to detecting the receiver, the device can upload to a remote monitoring device via the receiver at least one indicator of the wearer's current medical condition. (See, e.g., Specification, paragraphs 0038 and 0046.)

The device also can include a viewing screen connected to the processor. (See, e.g., paragraph 0033.) The screen can be activated both (a) manually by the wearer and (b) automatically by the processor detecting health indicator data outside of a predetermined normal range. The screen, moreover, can be configured to visually display, when activated, at least one indicator of the wearer's current medical condition.

**The Claims Define Over The Prior Art**

Independent Claims 1, 12, 19, and 25, as already noted, were deemed in the Office Action to be anticipated by Causey. Causey is directed to a medical device module for use in a system having a remote programmer and/or a personal data assistant (PDA). (See Abstract.) In various embodiments, the medical device module of Causey includes a processor coupled to a medical device interface for processing data received from a medical device. (See, e.g., paragraphs 0006-0026.) Applicants respectfully submit, however, that Causey fails to teach, either expressly or inherently, every feature recited in Claims 1, 12, 19, and 25, as amended.

For example, Causey fails to teach a wireless transmitter that can be activated either manually, by a user, or automatically when one or more health indicators lying outside of a predetermined normal range is detected. Moreover, Causey fails to teach that such a wireless transmitter, when activated, detects an in-range wireless receiver and, in response thereto, uploads to a remote monitoring device via the receiver at least one indicator of the user's current medical condition.

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In a portion noted at page 3 of the Office Action, Causey describes different communications links by which the processor of the aforementioned medical device module exchanges data via one or more input and output (I/O) ports:

"[I]n alternative embodiments, the I/O port 210 may use other data transfer technologies such as cables, fiber optics, RF, or the like. In still other embodiments, the data I/O port 210 may include multiple ports to support multiple communication protocols or methods, or may include a universal port capable of transmitting data in several different modes. In preferred embodiments, the stored data may be downloaded to (or new program instructions and data uploaded from) a computer, communication station, or the like. In alternative embodiments, the stored data may be downloaded to (or new program instructions and data uploaded from) an infusion pump, or the like." (Paragraph 98, lines 16-27.)

The quoted portion of Causey describes different modes of communication, but nothing in the description remotely relates to a wireless device configured to detect an available communications link. Elsewhere Causey describes an external device (an "external infusion device") that can be activated by RF signals transmitted by a component of the medical device module (an RF programmer). (See paragraph 0070, lines 7-18.) But this aspect of Causey's medical device module is the opposite of a device worn by a user, as with Applicants' invention, that detects an available communications device.

Moreover, Causey nowhere teaches a health monitoring device or method whereby a wireless transmitter is activated manually and/or automatically in response to the detection of one or more health indicators lying outside predetermined normal ranges, as recited in each of the amended independent claims. It follows, therefore, that Causey does not expressly or inherently teach a wireless transmitter that is worn by a patient and

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that, when activated either by the patient or automatically based on the patient's monitored condition, seeks to detect a receiver via which data relating to the patient's current condition can be uploaded to a remotely located monitoring device; that is, a remote device separate from the device worn by the patient.

A further difference between Causey and Applicants' invention is that Causey's wireless link, apart from how it is established, is intended to control an infusion device. (See, again, paragraph 0070.) This is quite different from detecting the presence of a communications link to upload health data giving a patient's current medical condition, as further recited in each of the amended independent claims.

Accordingly, Causey nowhere provides the features needed, for example, to assist a patient going into or already in a state of incapacity. With Applicants' invention, a patient wearing a health monitoring device having an activatable wireless device for conveying such data is able to either activate the device manually when the patient recognizes a worsening condition or rely on the device being automatically activated in response to the patient's monitored health indicators moving out of their normal range. A physician or emergency responder, accordingly, is able to assess the patient's condition even though the patient is incapacitated and unable to describe his or her current medical condition.

In other portions cited in the Office Action, Causey describes downloading data from one device to another:

"[P]rograms and data may be downloaded to a remote or local PC, laptop, station, or the like, for analysis and review by a MiniMed or a trained health care professional through the transmitter/receiver 1026. The data may also be downloaded through a Communication-Station 1008 to a remotely located computer 1006 such as a PC, lap top, or the like, over communication lines, by modem or wireless connection . . ." (Paragraph 0063, lines 18-26.)

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Elsewhere, in another portion noted in the Office Action, Causey describes sending an alarm signal to a healthcare provider:

"In further alternatives, either the characteristic monitor 2200 or the telemetered characteristic monitor transmitter 2100 may transmit an alarm to a remotely located device, such as a communication-station, modem or the like to summon help. In addition, further embodiments of the characteristic monitor 2200 may include the capability for simultaneous monitoring of multiple sensors. Data transmission may be to other devices or include the capability to receive data or instructions from other medical devices. Preferred embodiments, as shown in FIGS. 31 and 33, use wireless RF frequencies; however, alternative embodiments may utilize IR, optical, ultrasonic, audible frequencies or the like. Further embodiments may also use a wired connection, as shown in FIG. 32." (Col. 87, lines 34-48.)

Neither of the quoted portions, however, describe the various features recited in Claims 1, 12, 19, and 25, as amended. Neither the sending of an alarm nor the downloading of data is comparable to a wireless device that when activated by a patient, or automatically in response to the patient's condition, detects a wireless link and conveys information regarding the patient's current medical condition and needed by an attending physician or emergency assistor.

Causey further fails to expressly or inherently teach a viewing screen that also can be activated manually by a patient and/or automatically in response to detecting health indicator data outside of a predetermined normal range. Although, Causey mentions the use of visual displays, none of those described in Causey are activated manually by a patient or automatically in response to the detection of one or more health indicators

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lying outside predetermined normal ranges so as to display at least one indicator of the patient's current medical condition.

Accordingly, Causey fails to expressly or inherently teach every feature recited in independent Claims 1, 12, 19, and 25, as amended. Applicant respectfully maintains, therefore, that amended independent Claims 1, 12, 19, and 25 define over the prior art. Applicant further respectfully maintains that whereas each of the dependent claims depends from one of the amended independent claims while recited additionally features, each of the dependent claims likewise defines over the prior art.

### CONCLUSION

Applicant believes that, in view of the claim amendments presented herein, this application is now in full condition for allowance, which action is respectfully requested. Applicant requests that the Examiner call the undersigned if clarification is needed on any matter within this Amendment, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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J. Rodman Steele, Jr., Registration No. 25,931  
Richard A. Hinson, Registration No. 47,652  
AKERMAN SENTERFITT  
Customer No. 40987  
Post Office Box 3188  
West Palm Beach, FL 33402-3188  
Telephone: (561) 653-5000